UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

August 31, 2012

MEMORANDUM

Subject: Efficacy Review for Peraclean 5
EPA Reg. No. 54289-3
DP Barcode: D403003

From: Lorilyn M. Montford LM 9/4/12
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To: Marshall Swindell, PM 33/Karen Leavy
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Applicant: Evonik Degussa Corporation
299 Jefferson Road
Parsippany, NJ 07054-0677

FORMULATION FROM LABEL:

Active Ingredient	% by wt.
Hydrogen Peroxide	26.5%
Peroxyacetic Acid	4.9%
Inert Ingredients	68.6%
Total	100.0%

I BACKGROUND

The product, Peraclean 5 (EPA Registration No. 54289-3) is an EPA registered product. The product is registered for use as a hard surface disinfectant (bactericide, fungicide) and sanitizer for use in industrial, institutional, medical and non-medical environments. The product is also used for food preparation and animal care facilities. The applicant has submitted this amendment to add foaming sanitization applications for previously cleaned, hard non-porous food contact surfaces. The study was conducted at MicroBioTest located at 105 Carpenter Drive, Sterling, VA 20164.

This data package included a letter from the applicant dated, May 17, 2012, one study (MRID No. 488325-01), Statement of No Data Confidentiality Claim, Good Laboratory Practices compliance statement, and the proposed label.

II USE DIRECTIONS

The product is designed for sanitizing and disinfecting hard, non-porous surfaces, including bathroom surfaces, countertops, sinks, bed frames, shelves, tables, chairs, refrigerators, carts, pipelines, tanks, vats, filters, evaporators, aseptic equipment in dairies, breweries, packing equipment surfaces and eating establishments. The product is registered for use in food preparation areas, filtration and reverse osmosis filtration, poultry hatcheries, kennels, egg hatcheries, pulp and paper mill systems, barns, and the treatment of fruit and vegetables surfaces. The proposed label provides the following surface types for the use of this product: plastic (polyethylene and polypropylene), vinyl, linoleum, glazed porcelain, stainless steel, and glass. Directions on the proposed label provided the following instructions for the use of the product as a food contact sanitizer:

> Prepare a dilute solution by adding 1.5 to 2.3 fl oz. per 5 gallons of potable water. After preparing the use solution, add 1.5 to 10 fl oz. of AGRHO FM-2011 (the only approved foam-generating additive for use with PERACLEAN 5. Apply the solution as foam using commercially available foam generating equipment. Allow foam to contact surfaces at least one minute. For foot bath application, allow foam to remain on boot surfaces for one minute upon existing the bath. Drain items and or surfaces thoroughly.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Additional Bacteria)

There are cases where an applicant requests to make claims of effectiveness against additional bacteria for a product that is already registered as a sanitizing rinse for previously cleaned, food contact surfaces. DSS/TSS-5 standards are silent on this matter. Confirmatory test standards would apply. For sanitizing rinses for previously cleaned, food contact surfaces, 2 product samples, representing 2 different product lots,

must be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control.

IV COMMENTS ON SUBMITTED EFFICACY STUDIES

1. MRID 488325-01 "Germicidal and Detergent Sanitization Action of Disinfectants Test" for Food Contact Surfaces. Test Organism: *Escherichia coli,* ATCC 11229, for Peraclean 5 component and Foaming Agent (Ag-RHO FM 2011), by Kathryn D. Dormstetter. Study Completion Date: May 15, 2012. Project Identification Number: 529-110.

This study was conducted against *Escherichia coli* (ATCC 11229). Two lots (Lot nos. 8252041901 and 8252021501) of the product, Peraclean 5, were tested using the AOAC Official Methods of Analysis, Sixteenth ed. (1995) for testing the Germicidal and Detergent Sanitizing Action of Disinfectants Test for hard, non-porous, food contact surfaces (Protocol No. 529.1.04.24.12). Two lots (Lot Nos. R0956-158 and R0949-2011) of the foaming agent (Ag-RHO-FM 2011) were combined with the product lots to demonstrate efficacy. The product was prepared in two dilutions: 100 ppm (0.18 mL Peraclean 5 + 99 mL diluent + 0.15 mL foaming agent; and 180 ppm (0.32 mL Peraclean 5 + 99 mL diluent + 0.15 mL foaming agent). The diluent utilized in testing was 400±2.9% ppm AOAC Hard Water. Inoculum preparation was done according to AOAC methods. The test agent will be prepared and applied exactly as directed by the sponsor. Ninety-nine mL aliquots of the prepared test agent were transferred to sterile, 250 mL Erlenmeyer flasks. The flask was allowed to equilibrate at the appropriate contact temperature for at least 10 minutes. Triplicate flasks were prepared for each concentration of the prepared agent. One mL of bacterial suspension was added to each test flask. Appropriate swirling was done before adding the suspension, creating enough residual suspension to prevent pooling of suspension at a point of contact with the test water. One mL aliquots of the bacterial-test material mixture were transferred to neutralizer 30 seconds after the addition of the bacterial suspension. Neutralizer tubes were mixed well and serially diluted in phosphate buffer dilution water. Selected aliquots were plated in Tryptone Glucose Extract. All plates were incubated for two days at 37±2°C. Following incubation and storage, subculture plates were visually enumerated. Controls included those for numbers control, neutralizer effectiveness confirmation, sterility, and challenge microorganism confirmation.

V RESULTS

Lot No.	Concentration	Replicate	Avg. CFU/mL	Percent Reduction
8252041901/ R0956-158	100 ppm	1 2 3	$<5.0 \times 10^0$ $<5.0 \times 10^0$ $<5.0 \times 10^0$	99.999% 99.999% 99.999%
	180 ppm	1 2 3	$<5.0 \times 10^0$ $<5.0 \times 10^0$ $<5.0 \times 10^0$	99.999% 99.999% 99.999%
8252021501/ R0949-2011	100 ppm	1 2 3	$<5.0 \times 10^0$ $<5.0 \times 10^0$ $<5.0 \times 10^0$	99.999% 99.999% 99.999%
	180 ppm	1 2 3	$<5.0 \times 10^0$ $<5.0 \times 10^0$ $<5.0 \times 10^0$	99.999% 99.999% 99.999%

Starting Inoculum = 1.2×10^8 CFU/mL

VI CONCLUSIONS

The submitted efficacy data (MRID No. 488325-01) support the use of the product, Peraclean 5, as a foaming sanitizer against *Escherichia coli* (ATCC# 11229) on hard, non-porous surfaces in the presence of 400 ppm hard water for a contact time of 30 seconds at use concentrations of 100 ppm and 180 ppm. One of the two product lots tested was at least 60 days old at the time of testing. Bacterial reductions of at least 99.999 % over the parallel control were observed within 30 second contact time. Sterility controls did not show growth. The concentration of the active ingredient, at the time of testing, or upon receipt is absent. This information is necessary for comparison of the Confidential Statement of Formula, to the tested product, to the proposed label.

VII RECOMMENDATIONS

1. The proposed label claims are acceptable regarding use of the product, Peraclean 5, as a sanitizer with foaming application for previously cleaned hard, non-porous surfaces at 100 ppm and 180 ppm use concentrations for a contact time of 1 minute. These claims are acceptable as supported by the efficacy data provided.

2. The following changes are recommended on the proposed label:

- Under the section for Foam Sanitization, change the sentence beginning, "Examples included" to, "For example, uses that include operating conveyor belts, vertical or uneven surfaces…"

- Under the "Precautionary Statements" section of the proposed label, change "before eating, drinking, or using tobacco" to read "before eating, drinking, chewing gum, using tobacco, or using the toilet."

- Add ATCC numbers are required for all microorganisms in one of these locations,
    - on the data matrix;
    - the master label (as optional text) with the listing of the organisms claimed, or
    - as the final page of the master label (as optional text).

- Change "Pseudomonas Auriginosa" to "*Pseudomonas aeruginosa*."

- Change "*E. coli* 0157:H7" to "*E. coli* O157:H7."

- Change "*Salmonella choleraesuis*" to "*Salmonella enterica*"